Arizona State Board of Homeopathic Medical Examiners Substantive Policy Statement Regarding Pain Management Guidelines for Homeopathic Physicians Providing Pain Management for Patients with Pain SPS 07-01

This substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona administrative procedure act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under Arizona Revised Statutes § 41-1033 for a review of the statement.

Utilization of pharmaceutical medicine is a recognized practice modality of the Board as defined at ARS §32-2901(22). The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a treat to the individual and society and that inappropriate prescribing of controlled substances, including opioid analgesics may lead to drug diversion and abuse by individuals who use them for other than legitimate medical uses.

ARS §32-2951 prescribes guidance regarding the labeling and storage of controlled substances. The pain management policy addresses the Board's expectations that physicians incorporate safeguards into their practices to minimize the potential for abuse and diversion of controlled substances.

Finally, ARS §32-2933 provides professional conduct statutes that guide the Board in adjudicating complaints. Several of the conduct statutes relate to the provision of or over prescribing of controlled substances. When reviewing these types of complaints the Board relies on the patient record to determine the medical history and management of chronic pain in patients. The policy provides guidance regarding what should be contained in a medical record, instances where it may be necessary to terminate a patient from the treating physician's care, as well as definitions of pain related terminology.

The full text of the policy is attached to this document.

Adopted at the Regular Meeting of the Board on September 11, 2007

The Arizona Board of Homeopathic Medical Examiners Pain Management Guidelines SPS 07-01

Introduction

The diagnosis and treatment of pain is integral to the practice of medicine. The Arizona Board of Homeopathic Medical Examiners encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain because of terminal illness.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery, and in the treatment of chronic pain, whether due to cancer or non-cancer origins.

The following guidelines demonstrate the Board's desire to encourage physicians to administer controlled substances in the course of treating pain, without fear of disciplinary action from this Board when such treatment is provided within the accepted community standard of care.

These guidelines are based on the Federation of State Medical Boards Model Policy for the Use of Controlled Substances for the Treatment of Pain and the Consensus Statement on the Use of Opioids for the Treatment of Chronic Pain by the American Pain Society and the American Academy of Pain Medicine.

Policy for the Treatment of Pain

Section I: Preamble

The Board recognized that access to the highest quality medical care includes access to effective and appropriate pain relief. Appropriate up-to-date treatment modalities improve the quality of life for patients who suffer from chronic pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain.

When investigating allegations of inappropriate pain management, the Board gathers all relevant medical records and statements from the complainant and physician. The Board refers to current clinical practice guidelines and expert analysis when reviewing cases involving pain management. The Board judges the validity of the physician's treatment of the patient based on the outcome of the investigation, rather than solely on the quantity and duration of medication administration.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for chronic pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must document chronic pain associated with an objective pain generator and/or a recognized chronic pain syndrome. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of chronic pain.

The laws of the State of Arizona mandate that the Board protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who use them for other than legitimate medical use. Diversion of controlled substances should be a concern of every health professional, but efforts to stop diversion should not interfere with prescribing opioids when appropriate for chronic pain management. Attention to patterns of prescription requests and inappropriate drug seeking behavior can decrease the risk of diversion and abuse. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

The chronic pain management goal is to address the patient's pain along with other aspects of the patient's functioning, including physical, psychological, social and work-related factors. When managing chronic pain the physician should consider current clinical knowledge, medical research and the use of pharmacologic and multidisciplinary non-pharmacologic modalities. The physician should adjust the quantity and frequency of doses according to the intensity and duration of the pain. Physicians must recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

Section II: Guidelines

The following guidelines apply to the physician's treatment of chronic pain, including the long-term use of controlled substances:

Evaluation of the Chronic Pain Patient: Evaluation should include a pain history and assessment of the impact of pain on the patient, a directed physical examination, a review of previous diagnostic studies, a review of previous interventions, a drug history, and an assessment of coexisting diseases or conditions.

Treatment Plan: Treatment planning should be tailored to both the individual and the presenting problem. Consideration should be given to different treatment

modalities, such as a formal pain rehabilitation program, the use of behavioral strategies, the use of noninvasive techniques or the use of medications.

Informed Consent: The physician must discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. This discussion should include the risks of addiction/ abuse, not alleviating all pain, and treatment alternatives including the effects of no treatment.

Agreement for Treatment: There are circumstances in which the use of a documented verbal or written agreement between physician and patient outlining patient responsibilities may be necessary for safe and responsible opioid prescribing. Such an agreement should include:

- Urine serum medication levels and baseline screening when requested;
- Number and frequency of all prescription refills;
- Reasons for which drug therapy may be discontinued (e.g. violation of agreement);
- Requirement that the patient receive all controlled substance prescriptions from one physician and one pharmacy whenever possible.

Periodic Review: Review of treatment efficacy should occur periodically to assess any new information about the etiology of the pain or the patient's state of health, the functional status of the patient, continued analgesia, opioid side effects, quality of life, and indications of medication misuse. Periodic reexamination is warranted to assess the nature of the pain complaint and to ensure that opioid therapy is still indicated. Attention should be given to the possibility of a decrease in global function or quality of life because of opioid use.

Consultation: Consultation with a specialist in pain medicine or with a psychologist may be warranted, depending on the expertise of the practitioner and the complexity of the presenting problem. The management of chronic pain in patients with a history of addiction or a co-morbid psychiatric disorder requires special consideration, but does not necessarily contraindicate the use of opioids.

Medical Records: The physician must keep accurate, legible and complete records that provide sufficient information for another practitioner to assume continuity of the patient's care. These records should contain at a minimum the following;

- The medical history and physical examination;
- Diagnostic, therapeutic and laboratory results that support the diagnosis;
- Evaluation and consultations;
- Treatment objectives:

- · Discussion of risks and benefits:
- Documented verbal and/or written informed consent;
- Treatments
- Medications (including date, type, dosage and quantity prescribed);
- Instructions and agreements;
- Periodic reviews.

The physician must maintain current records in an easily accessible manner and the records must be readily available for review.

Termination from Medical Practice: Circumstances may arise which lead the prescribing physician to terminate the treating physician/patient relationship. In such cases, the physician has a medical and ethical responsibility to make an effort to ensure that the patient does not undergo uncontrolled, abrupt withdrawal from the prescribed controlled substance. This can be accomplished by tapering the medication, arranging for inpatient detoxification, or providing continued care and prescription(s) to cover a realistic, limited period during which the patient has the opportunity to find a new treating physician and/or obtain admittance to an opioid detoxification program.

Compliance with Controlled Substances Laws and Regulations: to prescribe, dispense or administer controlled substance, the physician must be licensed in the State and comply with applicable federal and State regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific ruled governing controlled substances as well as applicable State regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defines as follows:

Acute Pain: Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction: Addiction is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following; impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal psychological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain: Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be

associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence: Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudo addiction: The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse: Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance: Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.